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OFGS File No. : P/3120-9
Inventors : John D. Corbitt, Jr. and Lori A. Leonetti
Title : BREAST IMPLANT
Assignee :

Enclosed herewith please find the following documents in the above-identified application for United States Letters Patent:

13 Pages of Specification including Abstract and Claims
15 Numbered Claims Calculated as 15 Claims for Fee Purposes
1 Sheet of Drawing Containing Figures 1 to 6. (Formal)
X Declaration and Power of Attorney (signed)
X Priority is Claimed under 35 U.S.C. §119:
U.S. Provisional Appln 60/061,588 filed October 10, 1997
U.S. Provisional Appln 60/077,639 filed March 11, 1998
U.S. Provisional Appln 60/091,306 filed June 30, 1998
Convention Date _____ for _____ Appln. S.N. _____
_____ Certified Priority Application
X Verified Statement Claiming Small Entity Status under 37 C.F.R. §1.27.
_____ Assignment
X Return-Addressed Post Card
OFGS Check No. 6037, which includes the fee of $395.00, calculated as follows:

Basic Filing Fee:	$ 790.00
Additional Filing Fees:	
Total Number of Claims in Excess of 20, times $22:	
Number of Independent Claims in Excess of 3, times $82. . .	
One or More Multiple Dependent Claims: Total $270.	
Total Filing Fees or	$
Total Filing Fee Reduced 50% for Small Entity:	395.00
Assignment Recording Fee: $40	
TOTAL Filing Fee and Assignment Recording Fee:	$ 395.00

In the event the actual fee is greater than the payment submitted or is inadvertently not enclosed, or if any additional fee during the prosecution of this case is not paid, the Patent and Trademark Office is authorized to charge the underpayment to Deposit Account No. 15-0700.

EXPRESS MAIL CERTIFICATE

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail Post Office to Addressee (mail label #EE487234095US) in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on October 9, 1998:

Peter McGee
Name of Person Mailing Correspondence

Signature

October 9, 1998
Date of Signature

Respectfully submitted,

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FORM\DC24629

Serial or Patent No.: _____ OFGS File No. P/3120-9
Filing or Issue Date: _____
Applicant or Patentee: John D. Corbitt, Jr. and Lori A. Leonetti
For: BREAST IMPLANT

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
37 CFR 1.9(f) and 1.27(b) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor defined in 37 CFR 1.9(c) for purposes of paying reduced fees under 35 USC §41(a) and to the U.S. Patent and Trademark Office with regard to the invention entitled BREAST IMPLANT described

[xx] U.S. Patent Application filed herewith
[ ] U.S. Patent Application Serial No. _____ filed _____
[ ] U.S. Patent No. _____ issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed or licensed or am under an obligation under contract or law to assign, grant, convey or license any rights in the invention is listed below:

[xx] no such person, concern or organization
[ ] persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. 37 CFR 1.27

FULL NAME: _____
ADDRESS: _____
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

NAME: _____
ADDRESS: _____
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

I acknowledge the duty to file in this patent application or patent, notification of any change of status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 CFR 1.29(b)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC §1001, and that such willful false statements may jeopardize the validity of the patent application, any patent issuing thereon, or any patent to which this verified statement is directed.

John D. Corbitt, Jr.	Lori A. Leonetti	
Name of Inventor	Name of Inventor	Name of Inventor
Signature of Inventor	Signature of Inventor	Signature of Inventor
9 Oct 98	10/9/98	
Date	Date	Date

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FORM\DC24559

BREAST IMPLANT

This application claims the benefit of U.S. Provisional Application Serial No. 60/061,588, filed October 10, 1997, U.S. Provisional Application Serial No. 60/077,639, filed March 11, 1998, and U.S. Provisional Application Serial No. 60/091,306, filed June 30, 1998, the disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention:

The present invention relates to implantable prostheses. More particularly, the present invention relates to implantable breast prostheses designed to eliminate encapsulation and reduce scarring, and to replace tissue removed for purposes of biopsy or lumpectomy.

2. Description of the Related Art:

Breast prostheses are utilized for augmentation mammoplasty and in cosmetic surgery. Prostheses also are indicated in breast cancer surgery, such as lumpectomies, where a portion of the breast is removed and can leave some disfigurement if not replaced by a similar amount of tissue and/or augmentation material.

Similarly, biopsies can leave small dimples or imperfections if remedial steps are not taken. About 1 million breast biopsies are performed in the United

States annually. As a result, some 200,000 new breast cancers are diagnosed each year.

Known methods of augmentation mammoplasty utilize silicone or saline implants. These have been complicated by encapsulation of the implants, which can occur to varying degrees. Encapsulation produces a hard area of scar tissue around the implant, resulting in a rigid, abnormally-shaped mound beneath the breast tissue or pectoralis muscle, depending upon the placement of the implant.

Moreover, the known implant materials may not be indicated for replacement of smaller amounts of tissue, as would be required to prevent dimpling after biopsies, and they are not amenable to resizing. Further, the known implants are not capable of being implanted through a cannula or needle, and are not readily instilled with medicaments or chemical agents that would be useful in treating the patient.

Accordingly, a need exists for implants and methods that can be adapted for replacement of small as well as large amounts of tissue. A need also exists for implants that can be delivered through cannulae or needles, as well as being able to significantly reduce or eliminate encapsulation, resulting in a prolonged, aesthetically pleasing, soft mound below the breast tissue or pectoralis muscle. In addition, a need exists for implants into which useful substances, such as beneficial medications, chemical agents, hormonal treatments, and radiation media can be instilled to enhance the treatment capabilities of the implant in cancer and other breast pathology.

SUMMARY OF THE INVENTION

The present invention overcomes deficiencies of the prior art, such as those noted above, by providing an implant in which at least the outer portion of the implant, and as much the entire implant, is made of a resorbable material. The implant is sized and shaped to replace excised tissue, supports the surrounding tissue after implantation, and permits the in-growth of fibrous replacement tissue without encapsulation or with reduced scarring.

Accordingly, excised tissue is replaced by implanting an implant having at least an outer shell of resorbable material. The implant is sized and shaped to replace the excised tissue. The implant supports surrounding tissue while fibrous tissue replaces the resorbable portion of the implant.

Advantageously, the implant can be provided in the form of a compressible or non-compressible sponge, or a self-expanding foam. The implant can be instilled with beneficial materials, and can be inserted through a cannula, a needle, or directly inserted.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic elevation of a breast implant according to a preferred embodiment of the present invention.

Fig. 2 is a schematic view of a breast after implantation of the implant of Fig. 1.

Fig. 3 is a schematic view of a breast after implantation of an alternative embodiment of the implant of the present invention.

Fig. 4 is a cross-sectional schematic view of a breast implant according to a second alternative embodiment of the present invention.

Fig. 5 is a schematic view of a breast after implantation of the implant of Fig. 4.

Fig. 6 is a schematic view of a breast implant and a method of insertion according to further alternative embodiments of the present invention, particularly for cases involving the removal of smaller pieces of tissue such as by biopsy and lumpectomy.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring initially to Figs. 1 and 2, an implant **2** has an outer shell **4** made of a biosorbable material woven into a mesh. The inner contents of the implant are fluids such as saline and autologous blood products.

Outer shell **4** is made entirely of a biosorbable material, such as polyglycolic acid, for example, as set forth below. Over a period of approximately three weeks to six months, the outer shell will dissolve, leaving the inner contents **6** present inside the breast. Hard encapsulation will not occur because there is not a foreign body contained within the prosthetic space.

Referring to Fig. 3, implantation of an alternative embodiment of implant **2** is illustrated in

which the outer shell **4** includes both biosorbable material, and non-absorbable material, such as monofilament polypropylene fibers. Outer shell **4** is provided as a mesh or weave of the mixed material, surrounding contents **6** as described above. After a resorption period, contents **6** remain surrounded by a skeletal outer shell made up of non-absorbable fibers **8**, as shown in Fig. 3.

Advantageously, the proportions and spacing of the two types of materials can be altered to provide the desired properties of containment using a minimal amount of nonabsorbable material. Accordingly, the non-absorbable fibers **8** which remain after the biosorbable materials resorb will act as a scaffolding to allow the prosthesis to hold its shape; however, because of the limited amount of foreign material, encapsulation and scarring are decreased.

Referring to Figs. 4 and 5, a second alternative embodiment of the present invention is shown. A prothesis **10** features two capsules, a larger, outer capsule **12** made of biosorbable materials, and a smaller inner capsule **14** made of a non-absorbable material. Inner capsule **14** also can be made partially resorbable as in the first alternative embodiment above. Outer capsule **12** and inner capsule **14** can be separated by a thin layer **16** of saline or autologous fluids such as those described above. Inner capsule **14** surrounds a more permanent prosthesis **18** made of autologous fluids or saline, for example.

After implantation, outer capsule **12** dissolves, thus preventing hardening by encapsulation of the

prosthesis. The supply of fluid **16** between the capsules (a few to several cc.'s) is absorbed by the body once released by the dissolution of outer capsule **12**.

Referring to Fig. 6, a further alternative embodiment of the present invention includes an implant prosthesis **20** provided in the form of a matrix framework, such as a sponge or foam. The implant, which preferably is entirely biodegradable, has a porous structure which supports the surrounding tissue and provides a framework for the in-growth of fibrous tissue material.

According to a preferred embodiment, the implant is provided in the form of a sponge which can be modified by a surgeon prior to implantation, such as at a lumpectomy or biopsy site, simply by trimming the sponge to the appropriate size and shape. Alternatively, the implant can be a pre-shaped prosthesis of appropriate size, or an appropriate amount of foam. Advantageously, the implant can be modified to correspond to the breast tissue that either has been removed, requires replacement, or requires augmentation.

A preferred method of implantation is shown in Fig. 6, whereby the implant is elastically compressible, and is delivered using a cannula or needle **22** inserted into the breast. A single implant **20** is shown being compressed so as to fit within cannula **22**. A force is applied to drive the compressed implant distally through and out the distal end of the cannula into the implant site, where the resilient implant **20** expands to fill the implant site space.

The force for advancing the sponge through the cannula can be applied directly to the implant, or

indirectly using fluids, for example. Advantageously, the implant can be used in conjunction with stereotactic biopsy instrumentation, such as the ABBI System, the MIB System by USS, or the Mammotome System.

As a further alternative, the sponge implant of the present invention can form all or part of a larger implant, such as those described above, to form, for example, all or part of the outer shell **4** of implant **2**. Implantation using open procedures usually would be indicated when the sponge implant of the present invention is used as all or part of a larger implant. Accordingly, the sponge or implant would be placed directly into the biopsy or lumpectomy cavity.

In addition, the implant **20** can be provided in the form of a self-expanding foam, which can be injected by needle or through cannula **22** in a metered amount. Alternatively, a specialized applicator may be used to inject the desired amount of the foam. The amount of foam is preselected to allow sufficient expansion to fill the void left by the excision and support the surrounding tissue to prevent dimpling.

Following insertion of the implant, such as by an open method or one of the stereotactic methods described above, the resorbable implant occupies the breast tissue cavity and supports the surrounding tissue until such time as it is resorbed or biodegrades. After initial implantation, the patient's own fluids and fibroblast permeate the sponge prosthesis. In the case of a small implant, such permeation would occur naturally, subsequent to implantation. In the case of a larger implant, providing the implant at least partially

filled with fluids prior to implantation may be indicated.

Advantageously, the new prosthesis decreases encapsulation after implantation. Various biosorbable materials can be used in the implant of the present invention. Known biosorbable materials include the following:

polyglycolic acid (Dexon, Davis & Geck);
polyglactin material (Vicryl, Ethicon);
poliglecaprone (Monocryl, Ethicon); and
synthetic absorbable lactomer 9-1 (Polysorb, United States Surgical Corporation).

The examples above are designed to last varying lengths of time, after which time they are totally resorbed.

According to the present invention, these products may be mixed with one another or combined to provide various resorption times or gradients, and/or may be interrelated with non-absorbable materials, such as polypropylene or PTFFE (Gortex) material, for example. In an instance where a non-absorbable material is utilized, the non-resorbable implant section will remain partially intact as a permanent structure.

In each of the embodiments, the resorbable portions of the prosthesis ultimately biodegrade, and the patient is left with autologous tissue, some of which may have been implanted, or a permanent implant such as saline, as a filler for the biopsy cavity, thus preserving the contour of the breast and preventing indentation of the overlying skin.

The implants of the present invention further can be instilled, before or after implantation, with

indicated medicines and other chemical or diagnostic agents. Examples of such agents include, but are not limited to, antibiotics, chemotherapies, other cancer therapies, brachytherapeutic material for local radiation effect, x-ray opaque or metallic material for identification of the area, hemostatic material for control of bleeding, growth factor hormones, immune system factors, gene therapies, biochemical indicators or vectors, and other types of therapeutic or diagnostic materials which may enhance the treatment of the patient.

The present invention has been described particularly in connection with a breast implant, but it will be obvious to those of skill in the art that the invention can have application to other parts of the body, such as the face, and generally to other soft tissue or bone. Accordingly, the invention is applicable to replacing missing or damaged soft tissue, structural tissue or bone, or for cosmetic tissue or bone replacement.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

WHAT IS CLAIMED IS:

1. An implant for implantation in a human body comprising at least an outer shell of a resorbable material, the implant being formed to fit the shape and size of a cavity in the human body, the implant supporting tissue surrounding the cavity upon implantation and allowing for in-growth of fibrous tissue into and replacing at least the outer shell.

2. The implant of claim 1, wherein the entire implant is formed of the resorbable material.

3. The implant of claim 1, wherein the resorbable material is elastically compressible.

4. The implant of claim 1, wherein the resorbable material is formed from one of a self-expanding foam, a compressible sponge, and a non-compressible sponge.

5. The implant of claim 1, further comprising a core provided inside and surrounded by the resorbable material.

6. The implant of claim 4, wherein the core is filled with autologous material.

7. The implant of claim 1, wherein the implant is capable of carrying other substances such as radiation material, antibiotics, chemotherapies, cancer

therapies, hemostatic material, hormone therapies, and radiographic markers.

8. The implant of claim 1, further comprising at least one therapeutic or diagnostic substance.

9. The implant of claim 8, wherein the at least one substance is selected from the group consisting of radiation material, antibiotics, chemotherapies, cancer therapies, hemostatic material, hormone therapies, and radiographic markers.

10. A method for replacing excised tissue with an implant comprising the steps of:

forming the implant having at least an outer shell made of a resorbable material; and

implanting the implant so as to replace the excised tissue, the material supporting surrounding tissue upon implantation and allowing for in-growth of fibrous tissue.

11. The method of claim 10, wherein the entire implant is made of the resorbable material.

12. The method of claim 10, wherein the resorbable material is elastically compressible, and the step of implanting includes the step of compressing the resorbable material.

13. The method of claim 10, wherein the resorbable material is formed from a self-expanding foam,

and the step of implanting is performed by injection of the self-expanding foam.

14. The method of claim 10, further comprising the step of introducing into the implant at least one of a medicinal, therapeutic or diagnostic substance.

15. The method of claim 10, wherein the at least one substance is selected from the group consisting of radiation material, antibiotics, chemotherapies, cancer therapies, hemostatic material, hormone therapies, and radiographic markers.

BREAST IMPLANT

ABSTRACT OF THE DISCLOSURE

A breast implant has at least an outer shell which is composed of a resorbable material. The implant, which can be formed entirely of bioresorbable material, is sized and shaped to replace excised tissue. The implant supports surrounding tissue upon implantation, while allowing for in-growth of fibrous tissue to replace the implant. According to various alternative embodiments, the implant is elastically compressible, or can be formed from self-expanding foam or sponges, and can be implanted through a cannula or by injection, as well as by open procedures. The implant also is capable of carrying therapeutic and diagnostic substances.

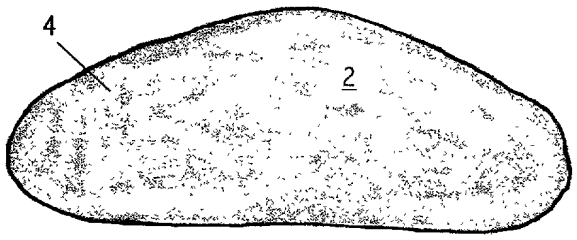

FIG. 1

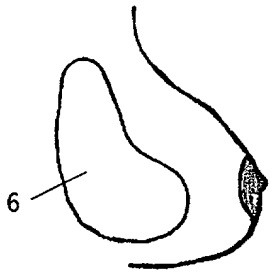

FIG. 2

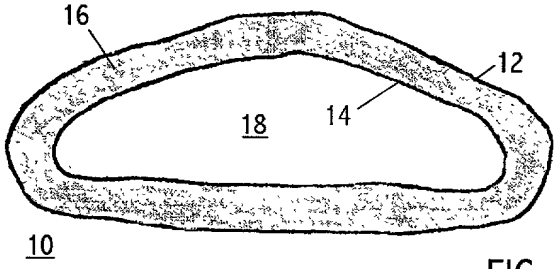

FIG. 4

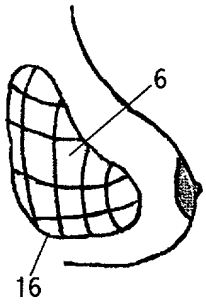

FIG. 3

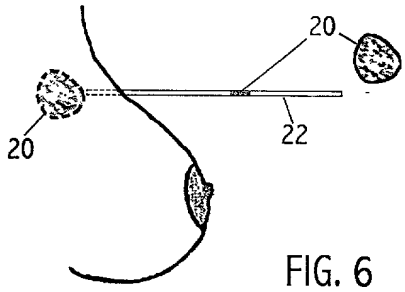

FIG. 6

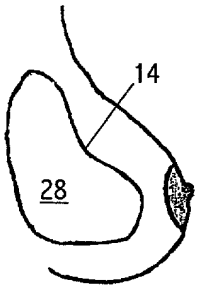

FIG. 5

UNITED STATES OF AMERICA COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION	OFOS FILE NO. P/3120-9

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; I verily believe that I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

BREAST IMPLANT

the specification of which is attached hereto, unless the following box is checked:

☐ was filed on _____ as United States patent Application Number or PCT International patent application number _____ and was amended on _____ (if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information known to be material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code §119 of any foreign application(s) for patent or inventor's certificate or United States provisional application(s) listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign or Provisional Application(s)

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 U.S.C.
U.S. Provisional	60/061,588	October 10, 1997	YES X NO ___
U.S. Provisional	60/077,639	March 11, 1998	YES X NO ___
U.S. Provisional	60/091,306	June 30, 1998	YES X NO ___

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

UNITED STATES APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

I hereby appoint customer no. 2352 OSTROLENK, FABER, GERB & SOFFEN, LLP, and the members of the firm, Samuel H. Weiner - Reg. No. 18,510; Jerome M. Berliner - Reg. No. 18,653; Robert C. Faber - Reg. No. 24,322; Edward A. Meilman - Reg. No. 24,735; Stanley P. Lieberstein - Reg. No. 22,400; Steven I. Weisburd - Reg. No. 27,409; Max Moskowitz - Reg. No. 30,576; Stephen A. Soffen - Reg. No. 31,063; James A. Finder - Reg. No. 30,173; William O. Gray, III - Reg. No. 30,944; Louis C. Dujmich - Reg. No. 30,625 and Douglas A. Miro - Reg. No. 31,643, as attorneys with full power of substitution and revocation to prosecute this application, to transact all business in the Patent & Trademark Office connected therewith and to receive all correspondence.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF SOLE OR FIRST INVENTOR	INVENTOR'S SIGNATURE	DATE
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RESIDENCE (City and either State or Foreign Country) Deerfield Beach, FL 33446		COUNTRY OF CITIZENSHIP U.S.A.
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FULL NAME OF THIRD JOINT INVENTOR (IF ANY)	INVENTOR'S SIGNATURE	DATE
RESIDENCE (City and either State or Foreign Country)		COUNTRY OF CITIZENSHIP
POST OFFICE ADDRESS		

☐ CONTINUED ON PAGE 2